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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,409

07/15/2004

Kenji Okada

YMOR:330

9556

27890 7590 01/16/2007
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EXAMINER

RAMILLANO, LORE J

ART UNIT

PAPER NUMBER

1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/501,409	Applicant(s) OKADA ET AL.	
	Examiner Lore Ramillano	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In applicant's preliminary amendment filed on 7/15/04, applicant amended claim
4. Claims 1-13 are pending in the application.

Claim Objections

2. Claim 7 is objected to because of the following informalities: "potion" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear because it cannot be determined whether the channel is rotatable about the axis?

Claims 1 and 13 are unclear because it cannot be determined whether the outer periphery is the same as the radially outer end portion of the channel? Furthermore, it appears that applicant's claim language (i.e. a channel; analysis area) is not consistent with applicant's drawings (particularly Fig. 1) because there appears to be more than one channel, analysis area, injection port, water absorbing member, and outer end portion. For example, because the channel is not continuous throughout the disk, applicant's drawings appear to depict more than one channel. This is a similar interpretation with the other structural limitations in applicant's drawings. Thus, based

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on applicant's claim language, applicant is claiming only one side of the disk or rather an apparatus with one channel, injection port, water absorbing member, analysis area, and outer end portion.

The language of claim 10 is confusing. Is applicant claiming a specific portion (i.e. inward portion of channel" or outer portion of channel?) of the channel is coated with a hydrophobic material?

Drawings

5. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the "analysis area" as described in the specification. While applicant indicates a "reagent portion" in the drawings by indicating it as number 7, it is unclear whether this numeral is also indicative of the "analysis area." Furthermore, the drawings do not accurately depict the claim language (see paragraph 3 above). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary

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to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 1-6, 8-10, and 13** are rejected under 35 U.S.C. 102(e) as being anticipated by Werner et al. ("Werner," US 7083920).

Werner discloses an optical bio-disc comprising: a channel (i.e. 128, Fig. 4), which extends from an injection port (i.e. 122, Fig. 3D) toward an outer periphery and rotatable about an axis by an external rotation means (i.e. column 2, lines 19-21) to cause a liquid specimen injected into the channel from the injection port to flow through an analysis area (i.e. 140, Fig. 4) provided midway in the channel to a radially outer end portion of the channel, wherein a water absorbing member is provided in the end portion of the channel (i.e. 145, Fig. 4).

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Werner further discloses a reagent reactive with a constituent of the liquid specimen in the analysis area (i.e. column 4, lines 10-21); a water absorbing material composed of a porous material, a blood coagulating agent (i.e. glass) for coagulating the liquid specimen and is bottlenecked (i.e. column 6, line 67 to column 7, line 3; Fig. 4); a portion of the channel is coated with a hydrophobic material (i.e. column 13, lines 17-25); a channel that includes a plurality of channels (i.e. 130 and 132, Fig. 4), which are connected to each other at the outer end portions; and an optical detector (i.e. 158, Fig. 3B).

8. **Claims 1-6 and 8-13** are rejected under 35 U.S.C. 102(e) as being anticipated by Valencia et al. ("Valencia," US Pub. No. 2003/0219713).

Valencia discloses an optical bio-disc comprising: a channel (i.e. 128, Fig. 4), which extends from an injection port (i.e. 122, Fig. 3D) toward an outer periphery and rotatable about an axis by an external rotation means (i.e. [0029]) to cause a liquid specimen injected into the channel from the injection port to flow through an analysis area (i.e. 140, Fig. 4) provided midway in the channel to a radially outer end portion of the channel, wherein a water absorbing member is provided in the end portion of the channel (i.e. 144, [0188]).

Valencia further discloses a reagent reactive with a constituent of the liquid specimen in the analysis area (i.e. [0058]); a water absorbing material composed of a porous material, a blood coagulating agent (i.e. glass, [0188]) for coagulating the liquid specimen and is bottlenecked (i.e. Fig. 4); a portion of the channel is coated with a hydrophobic material (i.e. [0188]); a channel that includes a plurality of channels (i.e.

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130 and 132, Fig. 5), which are connected to each other at the outer end portions; a valve (i.e. 310) that regulates the flow of the sample through the channels ([0313]); and an optical detector ([0060]).

9. **Claims 1-7 and 9-13** are rejected under 35 U.S.C. 102(e) as being anticipated by Braynin et al. ("Braynin," US Pub. No. 2003/0219713).

In Figs. 1-7, Braynin discloses an optical bio-disc comprising: a channel, which extends from an injection port (i.e. 22) toward an outer periphery and rotatable about an axis by an external rotation means (i.e. rotor) to cause a liquid specimen injected into the channel from the injection port to flow through an analysis area (i.e. column 8, lines 36-55) provided midway in the channel to a radially outer end portion of the channel, wherein a water absorbing member is provided in the end portion of the channel (i.e. flow path is made of hydrophilic material, column 7, lines 19-31).

Braynin further discloses in Figs. 1-7, a reagent reactive with a constituent of the liquid specimen in the analysis area (i.e. i.e. column 8, lines 36-55); a water absorbing material composed of a porous material, a blood coagulating agent (i.e. column 7, lines 19-31) for coagulating the liquid specimen; a portion of the channel is coated with a hydrophobic material (i.e. column 7, lines 19-31); a channel that includes a plurality of channels (i.e. channels connected by annual passage, column 8, lines 36-55), which are connected to each other at the outer end portions; a valve (i.e. column 8, lines 30-35) that regulates the flow of the sample through the channels ([0313]); having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion (column 6, line 64 to column 7, line 2); and an optical detector (19).

Claim Rejections - 35 USC § 103

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner.

Werner does not specifically disclose having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Werner by having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion because it would be desirable to provide a chamber for overflow.

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13. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Werner in view of Valencia.

Werner does not specifically disclose having a valve.

Valencia discloses an optical bio-disc, which comprises a valve (i.e. 310) that regulates the flow of the sample through the channels ([0313]).

Werner and Valencia are analogous art because they are from the same field of endeavor, biological assays and diagnostic assays and, in particular, to such assays conducted on optical bio-discs. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Werner with the valve limitation of Valencia as stated above, because it would be desirable to have a structural means to regulate the flow of the sample through the channels.

14. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Valencia.

Valencia does not specifically disclose having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Valencia by having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion because it would be desirable to provide a chamber for overflow.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano
Examiner
Art Unit 1743

1/6/07


Jill Warden
Supervisory Patent Examiner
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